John E. Flaherty
Jonathan M.H. Short
Carissa L. Rodrigue
MCCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 622-4444

Counsel for Plaintiffs AstraZeneca AB, AstraZeneca LP, KBI-E, Inc., and Pozen Inc.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA AB, ASTRAZENECA LP, KBI-E INC., and POZEN INC., Plaintiffs/Counter-Defendants, v. DR. REDDY'S LABORATORIES, LTD. INC. and DR. REDDY'S LABORATORIES, INC. Defendants/Counter-Plaintiffs.	CIVIL ACTION NO. 11-cv-02317-JAP-DEA (CONSOLIDATED FOR DISCOVERY PURPOSES WITH CIVIL ACTION NOS. 11-cv-04275-JAP-DEA AND 11-cv-06348 JAP-DEA) **Motion Day: September 17, 2012**

PLAINTIFFS' MEMORANDUM IN SUPPORT OF THEIR MOTION FOR LEAVE TO AMEND THEIR RESPONSE TO DRL'S INVALIDITY CONTENTIONS

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

OTHER AUTHORITIES

Plaintiffs seek leave to amend their Responses to Defendants' Invalidity Contentions by responding to the allegations of invalidity raised against claims 1, 5, 9-17, 22-23, 35, 48 and 50-55 of U.S. Patent 6,926,907 ("the '907 patent"). Amendment is necessary due to an oversight by prior counsel in not responding to certain invalidity contentions raised against the asserted claims of the '907 patent. Prior counsel has now withdrawn from this litigation and responsibility for the '907 patent has been transferred to counsel currently of record. Attached as Exhibit A to the Declaration of Enrique D. Longton in Support of Plaintiffs' Motion for Leave to Amend Their Response to DRL's Invalidity Contentions, filed concurrently herewith, is a copy of Plaintiffs' Proposed Amended Responses to DRL's Invalidity Contentions.

This is a Hatch-Waxman case. Plaintiffs AstraZeneca AB, AstraZeneca LP, KBI-Inc. (collectively, "AstraZeneca") and Pozen Inc. (collectively, "Plaintiffs") allege that defendants Dr. Reddy's Laboratories, Ltd. Inc. and Dr. Reddy's Laboratories Inc. (collectively, "DRL") infringed one Pozen patent and five AstraZeneca patents by filing Abbreviated New Drug Application No. 202461 ("DRL's ANDA") with the U.S. Food and Drug Administration ("FDA"). DRL's ANDA seeks approval to market a generic version of AstraZeneca's VIMOVO® prior to the expiration of Plaintiffs' patents. This action was commenced on April 21, 2011.

On November 17, 2011, Plaintiffs served their Disclosure of Asserted Claims (L. Pat. R. 3.6(b)). Plaintiffs asserted that DRL infringed 21 claims of the '907 patent (claims 1, 5, 9-17, 22-23, 35, 48 and 50-55).[1] In its November 23, 2012 Invalidity Contentions (L. Pat. R. 3.6(c)), DRL contended that each of the 21 asserted claims were invalid.

[1] Plaintiffs also asserted claims from the other five patents-in-suit which are not the subject of this motion.

In their January 17, 2012 Responses to DRL's Invalidity Contentions (L. Pat. R. 3.6(i)), Plaintiffs addressed each DRL contention, on a claim-by-claim basis, made against the five AstraZeneca patents. Unfortunately, Plaintiffs only responded to DRL's contentions (claims 1, 5, 9-17, 22-23, 35, 48 and 50-55 as being allegedly invalid) for 6 of the 21 asserted claims (claims 5, 15, and 52-55) of the '907 patent. This was an oversight. Plaintiffs seek to correct this oversight by fully responding to DRL's invalidity allegations for each asserted claim.

Leave should be granted for Plaintiffs to amend their Responses to DRL's Invalidity Contentions (L. Pat. R. 3.6(i)).

A. Legal Standard

Local Patent Rule 3.7 provides that amendment of contentions may be made if they are timely and upon a showing of good cause. As explained below, this motion is timely, and good cause exists for granting the motion. This Court has recognized that "Rule 3.7 is not a straightjacket into which litigants are locked from the moment their contentions are served." *See TFH Publications, Inc. v. Doskocil Mfg. Co., Inc.*, 705 F. Supp. 2d 361, 366 (D.N.J. 2010).

The District of New Jersey generally considers four factors when determining whether a party has shown good cause to amend its contentions: (1) the potential impact of a delay on the judicial proceedings; (2) the danger of unfair prejudice; (3) the importance of what is to be excluded; and (4) the reason for the delay and whether a party has been diligent. *Oy Ajat, Ltd. v. Vatech America, Inc.*, Civil Action No.: 10-4875 (PGS)(DEA), 2012 WL 1067900, *20 (D.N.J. Mar. 29, 2012).

Amending Plaintiffs' responses to DRL's invalidity contentions is proper and reasonable under the circumstances.

B. Plaintiffs' Motion Is Timely

Primary responsibility for litigating each of the six patents-in-suit on behalf of Plaintiffs was originally divided between two law firms. The '907 patent was the responsibility of prior counsel. On July 26 and July 27, 2012, prior counsel withdrew from the instant litigation, formally transferring primary responsibility for litigating the '907 patent to the attorneys currently of record. Upon assuming primary responsibility for litigating the '907 patent and review of the prior filings, the attorneys of record determined that Plaintiffs' Responses to DRL's Invalidity Contentions were incomplete because only claims 5, 15 and 52-55 were addressed in the Response. Recognizing this, Plaintiffs now timely seek leave of the Court to correct this oversight and address the invalidity contentions directed to all of the asserted claims of the '907 patent.

C. Plaintiffs' Proposed Amendment to Their Responses to DRL's Invalidity Contentions Will Not Introduce Any Delay into the Current Schedule

Plaintiffs' proposed amendment to their Responses to DRL's Invalidity Contentions will not cause any delay in the schedule. This litigation has been consolidated for discovery purposes with two separate lawsuits filed against two other sets of defendants: (1) Lupin Ltd. and Lupin Pharmaceuticals Inc. (11-04275-JAP-DEA) ("Lupin"); and (2) Anchen Pharmaceuticals, Inc. and Anchen Inc. (11-06348-JAP-DEA) ("Anchen"). As such, each litigation involves five common patents, each litigation is on the same schedule and they are all proceeding in the same manner.

Plaintiffs have fully responded to all of the invalidity contentions raised by Lupin and Anchen against the '907 patent. By this motion, Plaintiffs merely seek to fully respond to the invalidity contentions raised by DRL to Plaintiffs' asserted claims so that all of the invalidity contentions raised by each Defendant will be complete and consistent. Indeed, there is a high

degree of overlap in the references relied upon by each Defendant. As such, Plaintiffs' responses to these allegations are already in the case. Plaintiffs should be allowed to complete the "housekeeping" task of amending its responses to DRL's invalidity contentions so that the responses are complete and in line with what has already been filed in the consolidated litigations.

Moreover, allowing Plaintiffs to amend their responses to DRL's invalidity contentions will not cause any delay in the schedule. Claim construction and discovery are currently underway, but no *Markman* hearing has been held and no trial date has been set. No due dates have been set for affirmative or responsive expert reports on validity. No responses by DRL are required or contemplated by the schedule or the Local Patent Rules. DRL will have ample time to conduct discovery concerning the proposed amendments.

D. Amendment of Plaintiffs' Responses to DRL's Invalidity Contentions Will Not Unfairly Prejudice DRL but Plaintiffs Will Be Unfairly Prejudiced if They Are Not Permitted to Correct this Oversight

This litigation is still in its early stages. As such, DRL will not be unfairly prejudiced by Plaintiffs' proposed amendment to their response. DRL will have ample time to develop arguments in support of its invalidity contentions in its expert reports, the deadlines for which have yet to be scheduled. No rebuttal or reply to a response to invalidity contentions is contemplated by the Local Patent Rules. As such, no additional work is required on the part of DRL in response to Plaintiffs' proposed amendment to their responses to DRL's invalidity contentions. In fact, DRL will be prejudiced if Plaintiffs are not granted leave to amend their responses to DRL's invalidity contentions because DRL will not have proper notice as to the nature of Plaintiffs' responses to the invalidity contentions raised by DRL.

In contrast, Plaintiffs will be unfairly prejudiced if they are not permitted to amend their responses to DRL's invalidity contentions. At the moment, Plaintiffs could be

subject to a meritless motion for summary judgment of invalidity against all of the asserted claims to which they have not currently responded. Such a motion, if it were to be granted, would unfairly prejudice Plaintiffs because they have timely sought to correct an admitted oversight. The proposed amended response is directly related to the validity of the '907 patent and Plaintiffs merely seek to fully address DRL's invalidity contentions.

E. Plaintiffs' Full Response to DRL's Invalidity Contentions Is Important

It is important for Plaintiffs to fully respond to all of DRL's invalidity contentions against the asserted claims of the '907 patent. Plaintiffs' proposed amendment is directly related to the validity of the asserted claims of the '907 patent. It is important that Plaintiffs be granted leave to amend their responses to DRL's invalidity contentions for all of the reasons discussed above.

F. Plaintiffs Have Diligently Sought the Court's Leave to Amend Their Responses to DRL's Invalidity Contentions

As explained above, primary responsibility for litigating the '907 patent rested with prior counsel. On July 26 and July 27, 2012, prior counsel withdrew from the instant litigation, formally transferring primary responsibility for litigating the '907 patent to the attorneys currently of record. Upon assuming primary responsibility for litigating the '907 patent and review of the prior filings, the attorneys of record determined that Plaintiffs' Responses to DRL's Invalidity Contentions were incomplete because only claims 5, 15 and 52-55 (instead of claims 1, 5, 9-17, 22, 23, 35, 48 and 50-55) were addressed. Plaintiffs now timely seek leave of the Court to correct this admitted oversight and address the invalidity contentions directed to all asserted claims of the '907 patent.

* * *

Given that Plaintiffs have demonstrated (1) that the proposed amendment is timely, (2) it will not introduce any delay in the schedule, (3) it will not unfairly prejudice DRL, (4) it is important, (5) the reason for the delay and that Plaintiffs have been diligent, Plaintiffs respectfully request that the Court grant Plaintiffs' motion for leave to amend their Responses to DRL's Invalidity Contentions and enter the proposed Order enclosed with this motion.

Respectfully submitted,

Dated: August 17, 2012

s/John E. Flaherty
John E. Flaherty
Jonathan M.H. Short
Carissa L. Rodrigue
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 622-4444

Counsel for Plaintiffs AstraZeneca AB, AstraZeneca LP, KBI-E, Inc., and Pozen Inc.

Einar Stole
COVINGTON & BURLING LLP
1201 Pennsylvania Avenue, NW
Washington, DC 20004-2401
(202) 662-5095

Of Counsel for Plaintiffs AstraZeneca AB and AstraZeneca LP

Stephen M. Hash
VINSON & ELKINS LLP
2801 Via Fortuna
Suite 100
Austin, TX 78746-7568
(512) 542-8504Of

Counsel for Plaintiff Pozen Inc.

Henry J. Renk
FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, NY 10104-3800
(212) 218-2250

Of Counsel for Plaintiffs AstraZeneca AB, AstraZeneca LP, and KBI-E Inc.